### Food and Drug Administration, HHS

- (1) A weight average molecular weight of 2,000 to 2,300; and
- (2) A weight average molecular weight to number average molecular weight ratio of not more than 1.3. Copies of the method are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, orgo to: http:// www.archives.gov/federal register/ code of federal regulations/ ibr locations.html.
- (b) The additive is used to control mineral scale during the evaporation of beet sugar juice or cane sugar juice in the production of sugar in an amount not to exceed 3.6 parts per million by weight of the raw juice.

[53 FR 39456, Oct. 7, 1988; 53 FR 49823, Dec. 9, 1988]

#### §173.75 Sorbitan monooleate.

Sorbitan monooleate may be safely used in accordance with the following prescribed conditions:

- (a) The additive is produced by the esterification of sorbitol with commercial oleic acid.
- (b) It meets the following specifications:
  - (1) Saponification number, 145-160.
  - (2) Hydroxyl number, 193-210.
- (c) The additive is used or intended for use as follows:
- (1) As an emulsifier in polymer dispersions that are used in the clarification of cane or beet sugar juice or liquor in an amount not to exceed 7.5 percent by weight in the final polymer dispersion.
- (2) The additive is used in an amount not to exceed 0.70 part per million in sugar juice and 1.4 parts per million in sugar liquor.

[51 FR 11720, Apr. 7, 1986]

## Subpart B—Enzyme Preparations and Microorganisms

### § 173.110 Amyloglucosidase derived from Rhizopus niveus.

Amyloglucosidase enzyme product, consisting of enzyme derived from *Rhizopus niveus*, and diatomaceous silica as a carrier, may be safely used in food in accordance with the following conditions:

- (a) Rhizopus niveus is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, Rhizopus; species, niveus.
- (b) The strain of *Rhizopus niveus* is nonpathogenic and nontoxic in man or other animals.
- (c) The enzyme is produced by a process which completely removes the organism *Rhizopus niveus* from the amyloglucosidase.
- (d) The additive is used or intended for use for degrading gelatinized starch into constituent sugars, in the production of distilled spirits and vinegar.
- (e) The additive is used at a level not to exceed 0.1 percent by weight of the gelatinized starch.

# $\S 173.115$ Alpha-acetolactate decarboxylase ( $\alpha\text{-ALDC})$ enzyme preparation derived from a recombinant Bacillus subtilis.

The food additive alpha-acetolactate decarboxylase ( $\alpha$ -ALDC) enzyme preparation, may be safely used in accordance with the following conditions:

- (a) The food additive is the enzyme preparation derived from a modified  $Bacillus\ subtilis\ strain\ that\ contains\ the$  gene coding for  $\alpha\text{-}ALDC$  from  $Bacillus\ brevis$ .
- (b)(1) The manufacturer produces the additive from a pure culture fermentation of a strain of *Bacillus subtilis* that is nonpathogenic and nontoxigenic in man or other animals.
- (2) The manufacturer may stabilize the enzyme preparation with glutaraldehyde or with other suitable approved food additives or generally recognized as safe substances.
- (3) The enzyme preparation must meet the general and additional requirements for enzyme preparations in the *Food Chemicals Codex*, 4th ed., 1996, pp. 133–134, which is incorporated by reference. The Director of the Office of